

Le Vet BV
Wilgenweg 7
3421 TV Oudewater
Nederland

Sample-code(s), 2013081141 Raamsdonksveer, 05-09-2013

Manufacturer's batch certificate

Description of the product **Benakor F 5 mg tablets**
Pack size **Blister of 14 tablets (7 pcs)**
Product number **P3119** Registration number **Zul.Nr.:401022.00.00**
Recipe/filling number **R0958 U0664** Order number **PO 3521**
Batch number **13 H 201** Batch size **2977 pcs**
Batch customer **13 H 201**
Manufacturing/output date **08-2013 / 08-2013** Expiry date **01-2015**

Method	Description Parameter	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
<u>LAF005A</u>	<u>Average weight</u>		101 mg	100.0	92.5	107.5	95.0	105.0
<u>LAF005B</u>	<u>Uniformity of mass</u>							
	<i>Measured units</i>	20		informative value				
	<i>≥ 18 units</i>	conform		conform				
	<i>≤ 2 units</i>	conform		conform				
	<i>Variation</i>	5.2 %		informative value				
<u>LAF009A</u>	<u>Dimensions</u>							
	<i>Diameter</i>	4.5 mm			4.3	4.8	4.4	4.7
	<i>Height</i>	3 mm			2.8	3.2		
	<i>length</i>	9 mm		9	8.8	9.2	8.9	
<u>LAF010A</u>	<u>Shape</u>							
	<i>Appearance</i>	tablet		tablet				
	<i>Mark of division</i>	1, double sided		1, double sided				
	<i>Shape</i>	oblong		oblong				
<u>LAF011A</u>	<u>Colour</u>	yellow		yellow				
<u>LAF022A</u>	<u>Disintegration time</u>	4.22 min.				15		
<u>LAF023A</u>	<u>Hardness</u>	56 N			35	60		
<u>LAF024A</u>	<u>Friability</u>	0.2 %				1		
<u>LAV179A</u>	<u>Benazepriil</u>							
	<i>Benazepriil HCl</i>	4.9 mg/unit		5.0	4.75	5.35	4.85	5.25
	<i>Identification Benazepriil HCl</i>	positive		positive				
<u>LAV179B</u>	<u>Benazepriil impurities</u>							
	<i>Impurity C</i>	0.1 %				3.0		1.0
	<i>Impurity individual</i>	0.2 %				1.0		0.5
	<i>Impurities total</i>	0.5 %				2.0		1.0
<u>LAV800A</u>	<u>Water according to Karl-Fischer</u>	1.8 %				3.0		
<u>LAF004D</u>	<u>Content (pcs)</u>	14 pcs		14				

All mentioned limits are equal to or stricter than the limits mentioned in the available documentation. Additional items may be specified without actual impact on the product specifications. LAV901A = component(s) not tested; result declared on the basis of the production amounts. LAV903A = component(s) not tested; result is declared amount according the composition.

Produlab Pharma retains samples till 1 year after the expiry date. Records of the analysts are retained for 7 years and are available on request.

We hereby certify that the above information is authentic and accurate. This batch of product has been manufactured and analysed at a qualified third party site, packaging and further quality control being performed at the below mentioned site in full compliance with the EU GMP requirements and with the specifications as agreed with the marketing authorization holder of the importing country. The batch processing, packaging, and analysis records were reviewed and found to be in compliance with GMP.

No deviations with a direct impact on the product quality are applicable for this product batch.
The batch is released into the market.

Initials qualified persons:

Continuation on following page Page 1 of 2

AH_26114_1309051009





Le Vet BV
 Wilgenweg 7
 3421 TV Oudewater
 Nederland

Sample-code(s), 2013081141 Raamsdonksveer, 05-09-2013

Manufacturer's batch certificate

Description of the product	Benakor F 5 mg tablets	Registration number	Zul.Nr.:401022.00.00
Pack size	B blister of 14 tablets (7 pcs)	Order number	PO 3521
Product number	P3119	Batch size	2977 pcs
Recipe/filling number	R0958 U0664	Expiry date	01-2015
Batch number	13 H 201		
Batch customer	13 H 201		
Manufacturing/output date	08-2013 / 08-2013		

Continuation of previous page

Method	Description <i>Parameter</i>	Result	Unit	Target	Lower limit	Higher limit	Lower warning	Higher warning
--------	---------------------------------	--------	------	--------	----------------	-----------------	------------------	-------------------

Produlab Pharma bv, Forellenweg 16, NL-4941 SJ Raamsdonksveer Manufacturing licence 1401-BVEAK

P.J.A. Rompa
 Laboratory manager

H.J. Nootboom
 QA manager, QP

11 SEP 2013
[Signature]

